K011455

JUL 1 8 2001

p 1/2

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	Biomet, Inc. P.O. Box 587 Airport Industrial Park Warsaw, Indiana 46581-0587
CONTACT PERSON:	Tracy J. Bickel
DEVICE NAME:	Biomet® Oncology Salvage System (***OSS***) Taper Stacking Adapter
CLASSIFICATION NAME:	Prosthesis, hip, semi-constrained, metal/polymer, cemented (888.3350, 87 JDI) Prosthesis, knee, femorotibial, constrained, cemented, metal/polymer (888.3510, 87 KRO)

INTENDED USE:

1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved;
2. Correction of varus, valgus, functional, or post-traumatic deformity;
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement;
4. Ligament deficiencies;
5. Tumor resection;
6. Trauma
7. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques;

These devices are single use implants.

<u>These devices are to be used with bone cement unless a proximal femur is indicated for use (USA)</u>

DEVICE DESCRIPTION: The Biomet® Oncology Salvage System (***OSS***) offers a variety of component options for treatment of patients that require proximal femoral, distal femoral, total femur, or proximal tibial replacements, as well as, resurfacing components for the proximal tibia and distal femur.

The ***OSS*** Taper Stacking adapter is a device to allow for the stacking of shorter diaphyseal segments so that 1cm increments can be achieved for the expansion of the implant.

The adapter has a 3/8 thread externally, while having a smaller #12 thread internally. The outer threads connect to the joint/diaphyseal taper junction. The internal threads are used for the locking screw.

Eleven diaphyseal segment (K002757) lengths are available in 3cm, 4cm, and 5cm to 23cm in 2 cm increments. A set of two locking screws is packaged with each diaphyseal segment, which is composed of a small locking screw and a large locking screw. The small locking screw provides additional fixation for the stem/diaphyseal taper junction, and the large locking screw provides additional fixation for the diaphyseal/joint component taper junction. The ***OSS*** Taper Stacking Adapter will be used in conjunction with the small screw at the stem/diaphyseal junction to allow for the expansion of the implant by 1cm and the ability to add more segments.

*The stacking of diaphyseal segments should **not** exceed the longest segment cleared in K002757, which is 23cm.*

POTENTIAL RISKS: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Fracture of the component	Bone fracture	Tissue growth failure
Cardiovascular disorders	Hematoma	Infection
Implant loosening/migration	Metal sensitivity	Dislocation
Deformity of the joint	Excessive wear	Soft tissue imbalance
Delayed wound healing	Blood vessel damage	Nerve damage
Breakdown of the porous surface		

SUBSTANTIAL EQUIVALENCE: Direct comparison has been made to the following predicate system:

- Biomet® Oncology Salvage System- K002757

Biomet® Oncology Salvage System (***OSS***) is trademark of Biomet, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Tracy J. Bickel
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Re: K011455
Trade/Device Name: Biomet® Oncology Salvage System (OSS) Taper Stacking Adapter
Regulation Number: 888.3350, 888.3510
Regulatory Class: II
Product Code: JDI, KRO
Dated: May 10, 2001
Received: May 11, 2001

Dear Ms. Bickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011455
Device Name: **Biomet® Oncology Salvage System (*OSS*) Taper Stacking Adapter**
Indications for Use:

Indications:
1. Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis, or traumatic arthritis where one or more compartments are involved;
2. Correction of varus, valgus, functional, or post-traumatic deformity;
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement;
4. Ligament deficiencies;
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7. Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques;

These devices are single use implants.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Robert Chen MS for CMW
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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510(k) Number K011455